K042473

510(k) Summary

NOV 19 2004

SUBMITTER: COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004

CONTACT PERSON: Jack Ellison
Director, Regulatory and Quality
Phone: (303) 467-6306
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DATE PREPARED: September 2, 2004

DEVICE TRADE NAME: COBE Angel Whole Blood Separation System

COMMON/USUAL NAME: General Purpose Centrifuge for Clinical Use

CLASSIFICATION NAME: General Purpose Laboratory Equipment Labeled or Promoted for a Specific Medical Use (21 CFR 862.2050)

PREDICATE DEVICE: Medtronic Magellan™ Autologous Platelet Separator System (K021902)

DEVICE DESCRIPTION:

The COBE® Angel Whole Blood Separation System consists of a blood centrifugation device and associated disposable processing set and whole blood access kit. The device is intended to be used at the patient's point-of-care for the safe and rapid preparation of platelet poor plasma and platelet rich plasma from a sample of whole blood.

The Blood Access Kit contains syringes, needles, anticoagulant, and a site preparation kit for collecting the blood to be processed with the Angel System. The Processing Set utilizes a variable volume separation chamber that separates autologous whole blood into red blood cells, platelet poor plasma, and platelet rich plasma. The Processing Set is provided sterile with a non-pyrogenic fluid pathway, and is for single patient use only. The Processing Set consists of the pre-connected variable volume separation chamber, a tubing set with a platelet sensor/valve assembly, and a three-compartment reservoir bag to hold the blood products (whole blood, red blood cells, and platelet poor plasma). A syringe is provided to collect the platelet rich plasma.

The primary features of the Angel System hardware are the centrifuge well and lid, roller pump, platelet sensor, valve assembly driver, touch screen user interface, and emergency stop switch. The platelet sensor detects the presence of the separated blood components as they exit the variable volume separation chamber, and switches the position of a rotating valve in the Processing Set to channel the individual blood components into their respective collection containers.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

A comparison of device features and in-vitro test data demonstrate that the Angel Whole Blood Separation System is substantially equivalent to the currently marketed Medtronic Magellan Autologous Platelet Separator System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Jack Ellison
Director, Quality Assurance and Regulatory Affairs
COBE Cardiovascular, Inc.
14401 West 65th Way, Field Service
Arvada, CO 80004

NOV 19 2004

Re: k042473
Trade/Device Name: COBE® Angel Whole Blood Separation System
Regulation Number: 21 CFR § 862.2050
Regulation Name: General purpose laboratory equipment labeled or promoted for a specific medical use
Regulatory Class: I
Product Code: JQC
Dated: September 7, 2004
Received: September 13, 2004

Dear Mr. Ellison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of In Vitro Diagnostic Device Evaluation and Safety has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings and Precautions section of the device's labeling:

> The safety and effectiveness of this device for in vivo indications for use has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to

proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of other labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications For Use

510(k) Number (If known): K042473

Device Name: COBE® Angel Whole Blood Separation System

Indications For Use:

The COBE® Angel Whole Blood Separation System is intended to be used at the patient's point-of-care for the safe and rapid preparation of platelet poor plasma and platelet rich plasma from a sample of whole blood.

The plasma and concentrated platelets can be used for diagnostic tests.

Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042473